MAY - 3 2000

K000395

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: Einstein Processing and Review Workstation.

Establishment Name and Registration Number of Submitter

Name:	ELGEMS Ltd.
Registration Number:	9613299
Corresponding Official:	Dan Laor ELGEMS Ltd. P.O. Box 170 Tirat Hacarmel 30200 ISRAEL

Device Classification

Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography system (Computer)
Common Name:	Nuclear Medicine Workstation
Classification Class:	Class II

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Equivalent Devices

- Genie Processing and Review Workstation – K964012
- Xpert Processing Software, part of the VariCam gamma camera –K953801
- Hawkeye Option for Dual-Head Variable Gamma Camera – K991841

Device Description and Intended use

The Einstein Processing and Review Workstation is a computer workstation used for the display, processing, archiving, and of Emission Tomography images (data). Applications include: Planar Imaging, Whole Body Imaging, Tomographic (SPECT) Imaging, Positron Imaging by Coincidence, Attenuation Correction, and Image Registration.

Summary of Studies

Bench and clinical data show that the Einstein Processing and Review Workstation as full functionality and is operating as designed.

Conclusion

In the opinion of ELGEMS Ltd., the Einstein Processing and Review Workstation is substantially equivalent in terms of safety and effectiveness to the above mentioned legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Dan Laor
VP for Quality and Regulatory Affairs
Elgems, Ltd.
P.O. Box 170
Tirat Hacarmel,
Israel 30200

Re: K000395
Einstein Processing and Review Workstation
Dated: February 2, 2000
Received: February 7, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Laor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000395 ~~first submission~~

DEVICE NAME: **Einstein Processing and Review Workstation**

INDICATION FOR USE: The display, processing, archiving, and communication of data acquired by Emission Tomography cameras used in diagnostic radiology, including procedures for planar imaging, whole body imaging, tomographic (SPECT) imaging, positron imaging by coincidence, attenuation correction, and anatomical image registration.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000395

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)